FEB 1 8 2000

K000217

APPENDIX I

510(k) SUMMARY

SUMMARY OF THE SAFETY AND EFFECTIVENESS FOR ROYAL SHIELD PURPLE (PINK/BLUE) COLORED POWDERED LATEX EXAMINATION GLOVES WITH AND WITHOUT GRAPE SCENTING & WITH A PROTEIN LABELING CLAIM

Contact person : Ong Lay Mau

This summary of safety and effectiveness information is being submitted in accordance with the requirement of SMDA 1990.

Device Information:
Trade Name - ROYAL SHIELD COLORED POWDERED LATEX EXAMINATION GLOVES
Common Name - Exam gloves
Classification Name - Patient examination glove (per 21 CFR 880.6250)
Classification Information - Class I latex patient examination glove 80LYY, powdered and meeting all the requirements of ASTM-D3578-99 Standard Specification for Latex Examination Gloves for Medical Application.

Device Description:
Class I latex patient examination gloves 80LYY, powdered and meeting all the requirements of ASTM-D3578-99 Standard Specification for Latex Examination Gloves for Medical Application.

Intended Use of Device:
A medical glove to be worn on the hand of the health care and similar personnel to prevent contamination between health care personnel and patient.

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Technological Characteristics of Device:

1. Dimension

DIMENSION				
	Ambidextrous		Size Fitted	
Width	X-Small	70 mm +/- 10 mm	5.5	70 +/- 10 mm
	Small	80 mm +/- 10mm	6.0	76 +/- 10mm
	Medium	95 mm +/- 10mm	6.5	83 +/- 10mm
	Large	111mm +/- 10mm	7.0	89 +/- 10mm
			7.5	95 +/- 10mm
			8.0	102 +/- 10mm
			8.5	108 +/- 10 mm
			9.0	114 +/- 10mm
Length	230 mm min			
Thickness - Finger	0.08 mm min			
Palm	0.08 mm min			

2. Physical Properties (ASTM-D3578-99 Standard Specification for Latex Exam Gloves)

LOT #	TENSILE STRENGTH				ULTIMATE ELONGATION			
	AGED		**UNAGED**		**AGED**		**UNAGED**	
TESTED	SHIELD	ASTM	SHIELD	ASTM	SHIELD	ASTM	SHIELD	ASTM
X-SMALL								
0001041117	23.4	14.0	23.5	14.0	895	500	890	700
SMALL								
0001031117	24.4	14.0	24.0	14.0	907	500	884	700
MEDIUM								
0001042117	223.2	14.0	24.1	14.0	907	500	887	700

3. Water Tight Test Data

BATCH #	DATE TESTED	SAMPLING SIZE	LEAK STATUS	NUMBER LEAKED
Unaged Smpl				
0001041117 XS	4 JAN 00	125	Yes	2
0001031117 S	4 JAN 00	125	No	-
0001042117 M	4 JAN 00	125	Yes	2
Aged Smpl				
0001041117 XS	12 JAN 00	125	YES	2
0001031117 S	12 JAN 00	125	YES	1
0001042117 M	12 JAN 00	125	YES	3

The above figures are within the ASTM D-3578-99 requirements for latex exam gloves of 2.5% AQL.

4. Biocompatibility

The test results below show that the gloves meet FDA biocompatibility requirements:

BIOCOMPATIBILITY TESTS	RESULTS
Primary Dermal Irritation Test	Not a primary irritant
Skin Sensitization Study	Not a sensitiser

5. Residual Protein Level

TESTS	FDA ALLOWABLE LEVEL	CLAIMED LEVEL
ASTM D 5712-95	-	< 200 µg/g Range: 102 – 155 µg/g Mean: 125 µg/g

The data presented indicate that the Royal Shield Powdered latex examination glove

1. meets/exceeds ASTM- D3578-99 Standard Specifications For Latex Examination Glove,
2. meets FDA pinhole requirements,
3. meets the protein labeling claim level at <200 µg/g.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 8 2000

Shield Gloves Manufacturer (M) SDN BHD
c/o Ms. Janna P. Tucker
Official Correspondent
Tucker and Associates
198 Avenue De La D'emerald
Sparks, Nevada 89434-9550

Re: K000217
Trade Name: Royal Shield Non-Sterile Purple (Pink/Blue) Colored Powdered Latex Exam With Protein Labeling Claim [<200 mcg or less] with/without grapes scented
Regulatory Class: I
Product Code: LYY
Dated: January 19, 2000
Received: January 24, 2000

Dear Ms. Tucker:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP

regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

Applicant: Shield Gloves Manufacturer (M) Sdn Bhd.

510K Number: K000217

Device Name: Royal Shield Powdered Latex Examination Gloves WITH PROTEIN LABELING CLAIM [< 200 mg or Less] WITH/WITHOUT GRAPE SCENTED

Indications For Use :

This is a medical glove to be worn on the hand of health care and similar personnel to prevent contamination between health care personnel and the patient.

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Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use ..... OR Over-The-Counter..... X .....
Per 21 CFR 801.109

Pamela for Chin

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K000217